Course code: 02-EMS-VOAP-SP1 / 02-EMS-VOAP-SP2 **Plan position:** ……

A. INFORMATION ABOUT THE COURSE

B. Basic information

Name of course	Validation of Analytical Procedures
Field of studies	
Level of studies	
Profile of studies	General academic
Form of studies	Stationary
Specialty	
Unit responsible for the field of studies	Faculty of Chemical Technology and Engineering
Name and academic degree of teacher(s)	Łukasz Dąbrowski, Ph.D.
Introductory courses	
Introductory requirements	

C. Semester/week schedule of classes

Semester	Lectures (W)	Auditorium classes (Ć)	Laboratory classes (L)	Project classes (P)	Seminar (S)	Field classes (T)	Number of ECTS points
winter / summer	10		15				5

2. LEARNING OUTCOME

No.	Learning outcomes description	The reference to the learning outcomes of specific field of study	The reference to the learning outcomes for the area
KNOWLEDGE			
W1	Has a structured, theoretically underpinned knowledge of general understanding of validation of analytical procedures.	K_W03	P6S_WG
W2	Knows techniques, methods and parameters for the validation process.	K_W11	P6S_WG
SKILLS			
U1	Works individually and as part of a team.	K_U02	P6S_UO P6S_UK
U2	Selects and calculates appropriate parameters for validating the analytical procedure.	K_U11	P6S_UW
SOCIAL COMPETENCES			
K1	Is aware of the responsibility for jointly tasks, which are related to teamwork.	K_K04	P6S_KK P6S_KO

3. TEACHING METHODS

Multimedia lectures, laboratory calculations (classes) are performed by students under the supervision of academic staff.

4. METHODS OF EXAMINATION

Written colloquium from lectures and written reports from laboratories. The teacher may also change the form of assessment.

5. SCOPE

Lectures	The purpose of analytical procedure validation. Parameters related to the validation process, such as precision, accuracy, limit of detection, limit of quantification, specificity, selectivity, linearity, sensitivity, limits of detection and quantification, measurement uncertainty, systematic error, gross error, etc. The use of statistical tests during the validation procedure. Examples of the validation process.
Laboratories	Planning the validation process. Calculating basic parameters related to the validation process. Applying statistical tests in the validation process. Presenting analytical results and validation parameters.

6. METHODS OF VERIFICATION OF LEARNING OUTCOMES

LEARNING OUTCOME	Form of assessment					
	Oral examination	Written exam	Colloquium	Project	Presentation	Report of the experiments
W1			x			
W2			x			x
U1			x			x
U2			x			x
K1						x

7. LITERATURE

Basic literature	1. M.E. Schwartz, I.S. Krull, Handbook of Analytical Validation, CRC Press Taylor & Francis Group, Boca Raton, 2012 2. B. Magnusson (ed.), U. Örnemark (ed.), Eurachem Guide: The Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and Related Topics, 2nd ed. EURACHEM, 2014,
Supplementary literature	1. C.C. Chan, H. Lam, Y. C. Lee, X-M. Zhang ANALYTICAL METHOD VALIDATION AND INSTRUMENT PERFORMANCE VERIFICATION, John Wiley & Sons, Inc., Hoboke, 2004 2. USFDA (2019) Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products 3rd Edition U.S. Food and Drug Administration Foods Program October 2019. 3. Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed SANTE 11312/2021 v2026

8. TOTAL STUDENT WORKLOAD REQUIRED TO ACHIEVE EXPECTED LEARNING OUTCOMES EXPRESSED IN TIME AND ECTS CREDITS

Student's activity		Student workload– number of hours
Classes conducted under a	Participation in classes indicated in point 1B	25

direct supervision of an academic teacher or other persons responsible for classes	Supervision hours	10
Student's own work	Preparation for classes	35
	Reading assignments	25
	Other (preparation for exams, tests, carrying out a project etc)	30
Total student workload		125
	Number of ECTS points	**5**